IN THE CLAIMS

Listing of Claims:

This listing of claims will replace all prior versions and listings of claims in the application:

1. (Currently amended) A pharmaceutical aerosol formulation for use in a metered dose inhaler (MDI) comprising formoterol fumarate di-hydrate in suspension, a propellant and ethanol, wherein the formoterol fumarate di-hydrate ~~is provided having~~ has a water content of about 4.8 to 4.28% by weight.

2. (Currently amended) [[A]] The pharmaceutical aerosol formulation according to claim 1, further comprising a steroid in solution. ~~comprising formoterol fumarate di-hydrate in suspension, and a steroid in solution, a propellant and ethanol, wherein the formoterol fumarate di-hydrate is provided having a water content of about 4.8 to 4.28% by weight~~.

3. (Currently amended) [[A]] The pharmaceutical aerosol suspension formulation according to ~~claim 1 or~~ claim 2, ~~comprising formoterol fumarate di-hydrate in suspension, and a steroid in solution, a propellant and ethanol, wherein the formoterol fumarate di-hydrate is provided having a water content of about 4.8 to 4.28% by weight, and~~ wherein the formulation is capable of being dispensed from an MDI to provide [[an]] a Delivered dose of formoterol fumarate di-hydrate that has a variance of no more than +/- 25%, of the mean Delivered dose when the formulation is stored at 40°C and 75% relative humidity for up to 6 months.

4. (Currently amended) [[A]] The pharmaceutical aerosol suspension formulation according to claim 2, ~~any preceding claim comprising formoterol fumarate di-hydrate in suspension, and a steroid in solution, a propellant and ethanol, wherein the formoterol fumarate di-hydrate has a water content of about 4.8 to 4.28% by weight,~~ wherein the formulation is

capable of being dispensed from an MDI to provide [[an]] a Delivered dose of formoterol fumarate di-hydrate with a fine particle fraction of 30 to 70%.

5. (Currently amended) [[A]] The pharmaceutical aerosol suspension formulation according to claim 2, ~~any of the preceding claims comprising formoterol fumarate di-hydrate in suspension, and a steroid in solution, a propellant and ethanol,~~ wherein the formoterol fumarate di-hydrate is provided as particles having a water content of about 4.8 to 4.28% by weight suspended in the propellant and solvent, and wherein the formulation is capable of being dispensed from an MDI to provide a Delivered dose of the steroid that has a variance of no more than +/- 25%, of the mean Delivered dose when the formulation is stored at 40°C and 75% relative humidity for up to 6 months.

6. (Currently amended) [[A]] The pharmaceutical aerosol suspension formulation according to claim 5, ~~any of the preceding claims comprising formoterol fumarate di-hydrate in suspension, and a steroid in solution, a propellant and ethanol, wherein the formoterol fumarate di-hydrate has a water content of about 4.8 to 4.28% by weight, and~~ wherein the formulation is capable of being dispensed from an MDI to provide a Delivered dose of steroid containing a fine particle fraction of 30% to 70%.

7. (Currently amended) [[A]] The formulation according to ~~any of the preceding claims~~ claim 2, wherein the steroid is selected from the group consisting of budesonide, ciclesonide, mometasone, fluticasone, beclomethasone, flunisolide, loteprednol, triamcinolone, amiloride, rofleponide or a pharmaceutically acceptable salt or derivative of these active compounds, selected from mometasone furoate, fluticasone dipropionate, beclomethasone dipropionate, triamcinolone acetonide [[or]] and flunisolide acetate.

8. (Currently amended) [[A]] The formulation according to claim 7 wherein the steroid is fluticasone propionate.

9. (Currently amended) [[A]] The formulation according to claim 8 wherein the fluticasone proprionate is present in an amount of 0.05 to 2 % by weight of the formulation.

10. (Currently amended) [[A]] The formulation according to claim 1 or claim 2, ~~any of the preceding claims~~ wherein the formoterol fumarate di-hydrate is present in an amount of 0.001 to 0.1% by weight of the formulation.

11. (Currently amended) [[A]] The formulation according to according to ~~any of the preceding claims~~ claim 1 or claim 2 containing a cromone selected from the group consisting of a pharmaceutically acceptable salt of cromoglycinic acid, nedocromil, [[or]] and mixtures thereof.

12. (Currently amended) [[A]] The formulation according to claim 11 wherein the cromone is present in the formulation in an amount of 0.001 to 1%.

13. (Currently amended) [[A]] The formulation according to ~~any of the preceding claims~~ claim 1 or claim 2, wherein the propellant is selected from the group consisting of ~~example~~ fluorochlorocarbons, ~~such as trichloro-monofluoromethane (F11), dichlorodifluoromethane (F12), monochlorotrifluoromethane (F13), dichloro-monofluoromethane (F21), monochlorodifluoromethane (F22), monochloromonofluoromethane (F31), 1,1,2-trichloro-1,2,2-trifluoroethane (F113), 1,2-dichloro-1,1,2,2-tetrafluoroethane (F114), 1-chloro-1,1,2,2,2-pentafluoroethane (F115), 2,2-dichloro-1,1,1-trifluoroethane (F123), 1,2-dichloro-1,1,2-trifluoroethane (F123a), 2-chloro-1,1,1,2-tetrafluoroethane (F124), 2-chloro-1,1,2,2-tetrafluoroethane (F124a), 1,2-dichloro-1,1-difluoroethane (F132b), 1-chloro-1,2,2-~~

~~trifluoroethane (F133), 2-chloro-1,1,1-trifluoroethane (F133a), 1,1-dichloro-1-fluoroethane (F141b) and 1-chloro-1,1-difluoroethane (F142b),~~ alkanes, ~~such as propane, butane and isobutane,~~ fluorinated alkanes, and ~~such as octafluoropropane (F218) and in particular~~ hydrofluoroalkanes. ~~such as difluoromethane (HFA 32), pentafluoroethane (HFA 125), 1,1,2,2-tetrafluoroethane (HFA 134), 1,1,1,2-tetrafluoroethane (HFA 134a), 1,1,2-trifluoroethane (HFA 143), 1,1,1-trifluoroethane (HFA 143a), difluoroethane (HFA 152a), or 1,1,1,2,3,3,3-heptafluoropropane (HFA 227)~~.

14. (Currently amended) [[A]] The formulation according to claim 13 wherein the propellant is a hydrofluoroalkane of the general formula[[.]]:

CxHyFz (I);

in which x is the number 1, 2 or 3, y and z are each an integer ~~>==1~~ greater than or equal to (≥) 1, and y+z=2x+2.

15. (Currently amended) [[A]] The formulation according to claim 32 ~~13 or claim 14~~ wherein the propellant is HFA 134a or HFA 227 or a mixture thereof.

16. (Currently amended) [[A]] The formulation according to ~~any of the preceding claims~~ claim 1 or claim 2, wherein the propellant is employed in an amount of greater than 90% by weight.

17. (Currently amended) [[A]] The formulation according to ~~any of the preceding claims~~ claim 1 or claim 2, wherein the ethanol is present in amounts of less ~~that~~ than 2.5% by weight.

18. (Currently amended) [[A]] The formulation according to ~~any of the claims~~ claim 1 or claim 2 comprising a surfactant selected from the group consisting of oleic acid, lecithin, sorbitan trioleate, cetylpyridinium chloride, benzalkonium chloride, polyoxyethylene (20)

sorbitan monolaurate, polyoxyethylene (20) sorbitan monostearate, polyoxyethylene (20) sorbitan monooleate, polyoxypropylene/polyoxyethylene block copolymers, polyoxypropylene/polyoxyethylene/ethylenediamine block copolymers, and ethoxylated castor oil.

19. (Currently amended) [[A]] The formulation according to claim 18 wherein the surfactant is present in an amount of 0.0001 to 1% by weight.

20. (Previously presented) A pharmaceutical aerosol formulation for use in a metered dose inhaler (MDI) comprising formoterol fumarate di-hydrate in suspension, a propellant and ethanol, wherein the moisture content of the formulation is in the range of from 50 ppm to 800 ppm.

21. (Currently amended) A vial containing [[a]] the formulation according to claim 1 or claim 2. ~~as defined in any of the preceding claims~~.

22. (Currently amended) [[A]] The vial according to claim 21 in the form of an ~~aluminium~~ aluminum, uncoated container.

23. (Currently amended) [[A]] The vial according to claim 21 ~~or claim 22~~ adapted to be placed in a metered dose inhaler, and capable of delivering a dosage of formoterol fumarate di-hydrate of about 3 to 15 micro-grams.

24. (Currently amended) [[A]] The vial according to claim 21 ~~to 23~~ adapted to be placed in a metered dose inhaler, and capable of delivering a dosage of a steroid of about 10 to 1000 micro-grams per puff.

25. (Currently amended) [[A]] The vial according to claim 24 adapted to be placed in a metered dose inhaler, and capable of delivering a dosage of fluticasone proprionate of about 50 to 500 micro-grams per puff.

26. (Currently amended) A package comprising [[a]] the vial ~~as defined in~~ according to claim 21 ~~or claim 22 containing a formulation as defined in any of the preceding claims, and~~ comprising a label containing a dosage claim, wherein the mean Delivered dose of the active substances is no more than +/- 15% of the dosage ~~contained~~ stated [[in]] on the label.

27. (Currently amended) A metered dose inhaler containing [[a]] the vial according to claim 21. ~~as defined in any of the claims 21 to 25~~.

28. (Currently amended) A method of producing a pharmaceutical aerosol formulation according to claim 1 or claim 2, ~~or a vial as defined in any of the claims 1 to 25~~ comprising ~~the step of~~ drying the formoterol fumarate di-hydrate to a water content of 4.8 to 4.28%.

29. (New) The formulation according to claim 13, wherein the propellant is a fluorochlorocarbon selected from the group consisting of trichloro-monofluoromethane (F11), dichlorodifluoromethane (F12), monochlorotrifluoromethane (F13), dichloro-monofluoromethane (F21), monochlorodifluoromethane (F22), monochloromonofluoromethane (F31), 1,1,2-trichloro-1,2,2-trifluoroethane (F113), 1,2-dichloro-1,1,2,2-tetrafluoroethane (F114), 1-chloro-1,1,2,2,2-pentafluoroethane (F115), 2,2-dichloro-1,1,1-trifluoroethane (F123), 1,2-dichloro-1,1,2-trifluoroethane (F123a), 2-chloro-1,1,1,2-tetrafluoroethane (F124), 2-chloro-1,1,2,2-tetrafluoroethane (F124a), 1,2-dichloro-1,1-difluoroethane (F132b), 1-chloro-1,2,2-trifluoroethane (F133), 2-chloro-1,1,1-trifluoroethane (F133a), 1,1-dichloro-1-fluoroethane (F141b) and 1-chloro-1,1-difluoroethane (F142b).

30. (New) The formulation according to claim 13, wherein the propellant is an alkane selected from the group consisting of propane, butane and isobutene.

31. (New) The formulation according to claim 13, wherein the propellant is octafluoropropane (F218).

32. (New) The formulation according to claim 13, wherein the propellant is a hydrofluoroalkanes selected from the group consisting of difluoromethane (HFA 32), pentafluoroethane (HFA 125), 1,1,2,2-tetrafluoroethane (HFA 134), 1,1,1,2-tetrafluoroethane (HFA 134a), 1,1,2-trifluoroethane (HFA 143), 1,1,1-trifluoroethane (HFA 143a), difluoroethane (HFA 152a) and 1,1,1,2,3,3,3-heptafluoropropane (HFA 227).

33. (New) A metered dose inhaler containing the vial according to claim 22.